

REMARKS

The Examiner has rejected claims 26- 32 under 35 U.S.C. § 112 first paragraph, stating that the use of NaCl as allowed in the folding buffer represents a chaotropic agent. The Applicant has amended claim 26 to now claim a folding buffer which consists of the elements as claimed. The limitation of no chaotropic agent has been removed.

In reference to rejection to the use of the terms of art "chaotropic agent", the Applicant asserts that one of skill in the art would associate the terms of art "chaotropic agent" with an agent which causes a molecular structure to be disrupted. The quality of being a chaotropic agent is defined by function and is not merely inherent to an individual salt or compound. Certain salts are severely chaotropic in nature such as the thiocyanate salts. Sodium chloride is not inherently chaotropic and whether it is a chaotropic agent is mandated by the concentration used. The concentration of 1-2 M NaCl which is used in the Applicant's invention is not chaotropic in nature to TGF- β .

The use of the terms of art "chaotropic agent" and identification of NaCl in column 12 and column 30 of Krivan et al. US Patent No. 5,843,463 refers to an agent which is intended to disrupt molecular attraction forces of a protein to a solid gel support and thus allow it to be eluted. This is what is disclosed in Krivan and it is a different invention than that claimed and disclosed by the Applicant.

The reference Magnusson, et al. US Patent No. 4,455,381, discloses NaCl as a chaotropic agent in the context of its use to reduce non-specific binding interactions in an antibody based assay to determine IgE levels. The NaCl in Magnusson does not disrupt the peptides used in the assay otherwise the assay would not work. The chaotropic use in Magnusson is to disrupt interactions of molecules which are intended to be assayed. As asserted above by the Applicant, the disruptive function of the agent is what qualifies something as a chaotropic agent. The Applicant discloses NaCl as an agent which provides adequate osmotic force in the buffer used in the Applicant's process. If the NaCl functioned as a chaotropic agent in the present invention it would not allow folding of the TGF- β in the claimed process.

The terms of art, "chaotropic agent" for the elution buffer used in Krivan and assay buffer in Magnusson do not have the same meaning as NaCl in the refolding buffer use by the Applicant. The Applicant's use of NaCl does not disrupt molecular structures but contributes to the re-association and re-folding process of TGF- β in the present invention.

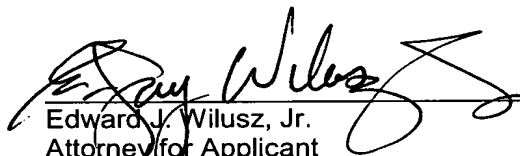
However, in the interest of expediency the Applicant has amended claim 26 without prejudice to further prosecute the subject matter of disclosed in a separate continuing application. The Applicant believes that the amended claims are well supported by the disclosure in the Application and that the claims do not read on any prior art.

The Applicants thus respectfully request that the Examiner withdraw the rejections under 35 U.S.C. § 112 first paragraph.

The Applicants believe that the application is now in condition for allowance and respectfully request early notice to that effect. If it will advance prosecution of the Application the Examiner is urged to contact the Applicants' undersigned counsel at the telephone number listed below.

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Respectfully submitted,


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